Notice of Allowability	Application No.	Applicant(s)	
	09/484,577	GORDON ET AL.	
	Examin r	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *10/14/03 and 11/12/03*.
2. ☒ The allowed claim(s) is/are *63-73, 77, 79, 81, 83 and 85-87 (renumbered 1-18)*.
3. ☒ The drawings filed on *18 January 2000* are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
2☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____
4☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5☐ Notice of Informal Patent Application (PTO-152)
6☒ Interview Summary (PTO-413), Paper No. *11122003* .
7☒ Examiner's Amendment/Comment
8☒ Examiner's Statement of Reasons for Allowance
9☐ Other .

DETAILED ACTION

1. Applicant's proposed amendment after final, filed 10/14/2003, is acknowledged and has been entered.
Claims 1-62 have been canceled.
Claims 63-87 have been added.
Claims 63-87 *are pending.*

2. Newly added claims 63-73, 77, 79, 81, 83 and 85 are directed to allowable products. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), newly added claims 86 and 87, directed to the process of using the patentable products and reciting subject matter previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 86 and 87 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

EXAMINER'S AMENDMENT

3. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

4. Authorization for this Examiner's Amendment was given in a telephone interview with Suzannah K. Sundby on November 12, 2003.

5. The Title has been amended to read
-- NUCLEIC ACIDS FOR THE DIAGNOSIS OF GIANT CELL ARTERITIS --

6. In the Claims:
The claims have been amended as follows:

1-62. (Canceled).

63. (Previously added) An isolated or recombinant nucleic acid consisting of SEQ ID NO:3, or its complement.

64. (Previously added) An isolated or recombinant nucleic acid encoding the polypeptide consisting of SEQ ID NO:4, or its complement.

65. (Previously added) An expression vector comprising an isolated or recombinant nucleic acid of claim 63 operably linked to a promoter in the sense orientation.

66. (Previously added) An expression vector comprising an isolated or recombinant nucleic acid of claim 64 operably linked to a promoter in the sense orientation.

67. (Previously added) A transformed cell comprising the isolated or recombinant nucleic acid of claim 63.

68. (Previously added) A transformed cell comprising the isolated or recombinant nucleic acid of claim 64.

69. (Previously added) A transformed cell comprising the expression vector of claim 65.

70. (Previously added) A transformed cell comprising the expression vector of claim 66.

71. (Previously added) A heterologous nucleic acid comprising the isolated or recombinant nucleic acid of claim 63.

72. (Previously added) A heterologous nucleic acid comprising the isolated or recombinant nucleic acid of claim 64.

73. (Currently amended) A nucleic acid probe ~~that is 10 to~~ consisting of 20 to 30 or more contiguous nucleotides of the isolated or recombinant nucleic acid of claim 63.

74-76. (CANCEL)

77. (Currently amended) A nucleic acid probe ~~that is~~ consisting of greater than 50 contiguous nucleotides of the isolated or recombinant nucleic acid of claim 63.

78. (CANCEL)

79. (Currently amended) A nucleic acid probe ~~that is between~~ consisting of about 15 to about 200 contiguous nucleotides of the isolated or recombinant nucleic acid of claim 63.

80. (CANCEL)

81. (Currently amended) A nucleic acid probe ~~that is between~~ consisting of about 25 to about 100 contiguous nucleotides of the isolated or recombinant nucleic acid of claim 63.

82. (CANCEL)

83. (Currently amended) A nucleic acid probe ~~that is between~~ consisting of about 35 to about 75 contiguous nucleotides of the isolated or recombinant nucleic acid of claim 63.

84. (CANCEL)

85. (Currently amended) A kit for detecting the presence of nucleic acid sequences associated with giant cell arteritis comprising at least one of the following:

(a) an isolated or recombinant nucleic acid consisting of SEQ ID NO:3, or its complement;

(b) an isolated or recombinant nucleic acid encoding the polypeptide consisting of SEQ ID NO:4, or its complement;

(c) a nucleic acid ~~that is 10 to~~ consisting of 20 to 30 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (a);

~~(d) a nucleic acid that is 10 to 20 to 30 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(e) a nucleic acid that is 10 to 50 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (a);~~

~~(f) a nucleic acid that is 10 to 50 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(g)~~ a nucleic acid ~~that is~~ consisting of greater than 50 contiguous nucleotides of the isolated or recombinant nucleic acid of (a);

~~(h) a nucleic acid that is greater than 50 contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(i)~~ (e) a nucleic acid ~~that is between~~ consisting of about 15 to about 200 contiguous nucleotides of the isolated or recombinant nucleic acid of (a);

~~(j) a nucleic acid that is between about 15 to about 200 contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(k)~~ (f) a nucleic acid ~~that is between~~ consisting of about 25 to about 100 contiguous nucleotides of the isolated or recombinant nucleic acid of (a); or

~~(l) a nucleic acid that is between about 25 to about 100 contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(m)~~ (g) a nucleic acid ~~that is between~~ consisting of about 35 to about 75 contiguous nucleotides of the isolated or recombinant nucleic acid of (a); ~~or~~

~~(n) a nucleic acid that is between about 35 to about 75 contiguous nucleotides of the isolated or recombinant nucleic acid of (b),~~

and instructional material.

86. (Currently amended) A method for diagnosing giant cell arteritis comprising
providing a nucleic acid sample from an arteritis lesion biopsy,
transferring the nucleic acid sample to a membrane, contacting the membrane with at least one nucleic acid probe selected from the group consisting of

(a) an isolated or recombinant nucleic acid consisting of SEQ ID NO:3, or its complement;

(b) an isolated or recombinant nucleic acid encoding the polypeptide consisting of SEQ ID NO:4, or its complement;

(c) a nucleic acid ~~that is 10 to~~ consisting of 20 to 30 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (a);

~~(d) a nucleic acid that is 10 to 20 to 30 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(e) a nucleic acid that is 10 to 50 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (a);~~

~~(f) a nucleic acid that is 10 to 50 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(g)~~ a nucleic acid ~~that is~~ consisting of greater than 50 contiguous nucleotides of the isolated or recombinant nucleic acid of (a);

~~(h) a nucleic acid that is greater than 50 contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(i)~~ (e) a nucleic acid ~~that is between~~ consisting of about 15 to about 200 contiguous nucleotides of the isolated or recombinant nucleic acid of (a);

~~(j) a nucleic acid that is between about 15 to about 200 contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(k)~~ (f) a nucleic acid ~~that is between~~ consisting of about 25 to about 100 contiguous nucleotides of the isolated or recombinant nucleic acid of (a); or

~~(l) a nucleic acid that is between about 25 to about 100 contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(m)~~ (g) a nucleic acid ~~that is between~~ consisting of about 35 to about 75 contiguous nucleotides of the isolated or recombinant nucleic acid of (a); ~~or~~

~~(n) a nucleic acid that is between about 35 to about 75 contiguous nucleotides of the isolated or recombinant nucleic acid of (b),~~

and detecting whether the nucleic acid probe hybridizes to the nucleic acid sample on the membrane; wherein specific hybridization is diagnostic for giant cell arteritis.

87. (Currently amended) A method for diagnosing giant cell arteritis or predisposition for giant cell arteritis in a subject comprising
obtaining a nucleic acid sample from the subject,
contacting the nucleic acid sample with at least one nucleic acid probe selected from the group consisting of

(a) an isolated or recombinant nucleic acid consisting of SEQ ID NO:3, or its complement;

(b) an isolated or recombinant nucleic acid encoding the polypeptide consisting of SEQ ID NO:4, or its complement;

(c) a nucleic acid ~~that is 10 to~~ consisting of 20 to 30 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (a);

~~(d) a nucleic acid that is 10 to 20 to 30 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(e) a nucleic acid that is 10 to 50 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (a);~~

~~(f) a nucleic acid that is 10 to 50 or more contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(g)~~ a nucleic acid ~~that is~~ consisting of greater than 50 contiguous nucleotides of the isolated or recombinant nucleic acid of (a);

~~(h) a nucleic acid that is greater than 50 contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(i)~~ (e) a nucleic acid ~~that is between~~ consisting of about 15 to about 200 contiguous nucleotides of the isolated or recombinant nucleic acid of (a);

~~(j) a nucleic acid that is between about 15 to about 200 contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(k)~~ (f) a nucleic acid ~~that is between~~ consisting of about 25 to about 100 contiguous nucleotides of the isolated or recombinant nucleic acid of (a); or

~~(l) a nucleic acid that is between about 25 to about 100 contiguous nucleotides of the isolated or recombinant nucleic acid of (b);~~

~~(m)~~ (g) a nucleic acid ~~that is between~~ consisting of about 35 to about 75 contiguous nucleotides of the isolated or recombinant nucleic acid of (a); ~~or~~

~~(n) a nucleic acid that is between about 35 to about 75 contiguous nucleotides of the isolated or recombinant nucleic acid of (b),~~

and detecting whether the nucleic acid probe hybridizes to the nucleic acid sample; wherein specific hybridization is diagnostic for giant cell arteritis or predisposition to giant cell arteritis.

REASONS FOR ALLOWANCE

7. The following is an Examiner's Statement of Reasons for Allowance:

Applicant's amendment filed October 14, 2003, obviated the previous rejections of record. It is noted that the phrase "its complement" is interpreted to be the full length complement of the sequence recited. The Examiner's amendment set forth supra places the application fully in condition for allowance.

Accordingly, the instant claims are deemed allowable.

8. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
November 12, 2003

Phillip Gambel
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PRIMARY EXAMINER
TECH CENTER 1600
11/12/03